12/18/98

MEMORANDUM

SUBJECT: **Endosulfan**. List A Reregistration Case 0014. Chemical No. 079401.
Product Chemistry Chapter for the Reregistration Eligibility Decision.
DP Barcode D250578.

FROM: K. Dockter, Chemist
Reregistration Branch 2
Health Effects Division [7509C]

THRU: Alan Nielsen, Branch Senior Scientist
Reregistration Branch 2
Health Effects Division [7509C]

TO: Phil Budig, PM 60
Special Review and Reregistration Division [7508W]

Attached is the Product Chemistry Chapter for the endosulfan [6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide] RED. The chapter was assembled by Dynamac Corporation under the supervision of RRB2, HED. The data assessment has undergone secondary and tertiary review and has been revised to reflect Agency policies. Most product chemistry data requirements remain outstanding.

Attachment: Reregistration Eligibility Decision: Product Chemistry Considerations

cc [with Attachment]: RF, Reg. Std. File, SF, Dockter, Deschamp, Phil Budig; SRRD.

RD/I RRB2 Endosulfan RED Team: P. Deschamp, [the TL], D. Liem, K. Dockter, J. Arthur, S. Devito.
7509C:RRB2:CM2:Rm718M:57886:KD/kd:
ENDOSULFAN.RED[879]

ENDOSULFAN

Shaughnessy No. 079401; Case 0014

Reregistration Eligibility Decision (RED) Document; Product Chemistry Considerations

July 1, 1998

Contract No. 68-D4-0010

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

ENDOSULFAN

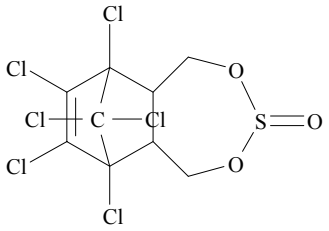
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 079401; Case No. 0014

DESCRIPTION OF CHEMICAL

Endosulfan [6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide] is a broad-spectrum insecticide/acaricide registered for use on a variety of field, fruit, and vegetable crops.



Empirical Formula:	$C_9H_6Cl_6O_3S$
Molecular Weight:	406.95
CAS Registry No.:	115-29-7
Shaughnessy No.:	079401

IDENTIFICATION OF ACTIVE INGREDIENT

Pure endosulfan is a colorless solid with melting points of 106-110 C (isomer I, alpha) and 208-210 C (isomer II, beta). Technical endosulfan is a mixture of the two isomers and is a tan or light brown to dark brown solid with a melting point of 70-100 C, specific gravity of 1.745 at 20 C, octanol/water partition coefficient (K_{ow}) of 1.1 x 10^5, and vapor pressure of 1 x 10^{-5} mm Hg at 25 C. Technical endosulfan is insoluble in water but is readily soluble in most organic solvents including xylene, kerosene, chloroform, methyl chloride, acetone, benzene, carbon tetrachloride, alkylbenzenes, methanol, toluene, amyl acetate, methylene chloride, dioxane, chlorobenzene, heptane, acetic acid, and ethanol at 20 C. Endosulfan decomposes to sulfur dioxide and endosulfan alcohol in the presence of acids, alkalis, and moisture.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 12/4/98 identified seven endosulfan manufacturing-use products (MPs) registered under Shaughnessy No. 079401; the registered

endosulfan MPs are listed below in Table 1. Only the registered MPs listed below are subject to a reregistration eligibility decision.

Table 1. Registered Endosulfan Manufacturing-Use Products.

Formulation	EPA Reg. No.	Registrant
96% T	45639-168 [a]	AgrEvo USA Company
95% T	279-2306	FMC Corporation
95% T	19713-319 [b]	Drexel Chemical Company
95% T	11678-5	Makhteshim Chemical Works Limited
35% FI	11678-25	
95%T	10163-223[c]	Gowan Co.
95%T	34704-799[c]	Platte Chemicl Co., Inc.

[a] Transferred from Hoechst Celanese Corporation (EPA Reg. No. 8340-13; 9/17/94).
[b] Transferred from Velsicol Agricultural Chemicals (EPA Reg. No. 876-201; 6/6/91).
[C] The adequacy of the data bases for the source materials for these repacks will be confirmed at the time of RED issuance.

REGULATORY BACKGROUND

A Reregistration Standard dated 9/17/81 and Guidance Document dated 4/82 were issued for endosulfan requiring additional generic and product-specific product chemistry data for the FMC, Makhteshim, Hoechst, and Velsicol MPs. The Endosulfan Reregistration Standard Update dated 8/9/90 reviewed data submitted in response to the Guidance Document and summarized the outstanding data requirements for the reregistration of endosulfan. Additional data were required concerning OPPTS 830.1550, 1600-1620, 1670, 1700, 1800, 6314, 6316, and 6320 for the Hoechst 96% T; all product chemistry data requirements except 830.7840 for the FMC 95% T; OPPTS 830.1600-1620, 1670, 1700, 1800, and 6320 for the Makhteshim 95% T; and OPPTS 830.1550, 1600-1650, 1670, 1750, and 1800 for the Makhteshim 35% FI. Although the Update reported that the Velsicol technical product had been canceled and did not address data requirements for Velsicol, the product was actually transferred to Drexel. The Hoechst technical product was transferred to AgrEvo subsequent to issuance of the Endosulfan Update.

In addition, Data Call-Ins (DCIs) were issued concerning the potential for formation of chlorinated dibenzo-p-dioxins and dibenzofurans (Dioxin DCI dated 6/87), and hexachlorobenzene and pentachlorobenzene (HCB/PCB DCI dated 9/92) in technical endosulfan products. Initial data indicate that dioxins are not likely to form because of the low temperatures and acidic conditions during the manufacture of endosulfan; however, HCB/PCBs may be present as impurities in the starting materials or may be formed from reactions of impurities present in the starting materials. Recent analyses showed that HCB levels found were <75-290 ug/kg, and PCB levels found were 1000-4900 ug/kg.

The current status of the product chemistry data requirements for the endosulfan manufacturing-use products is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Pertinent product chemistry data requirements remain unfulfilled for each of the registered MPs of endosulfan. Additional data are required concerning OPPTS 830.1550, 1600-1620, 1750, 6314, 6316, 6320, and 7050 for the AgrEvo 96% T; OPPTS 830.1550, 1700, 1750, 1800, 6314, 6317, 7000, 7050, and 7550-7570 for the Drexel 95% T; OPPTS 830.1550, 1700, 1750, 1800, 6320, and 7050 for the Makhteshim 95% T/TGAI; and OPPTS 830.1550, 1600, 1650, 1670, 1750, and 1800 for the Makhteshim 35% FI. All product chemistry data are required for the FMC 95% T, Gowan's 95% T, & Platte's 95% T, and these three registrants must specify whether their products are repackaged from an EPA-registered product or produced by these three registrants. Provided that the registrants submit the data required in the attached data summary tables for the endosulfan MPs, and either certify that the suppliers of beginning materials and the manufacturing processes for the MPs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, CBRS has no objections to the reregistration of endosulfan with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).:	6087
Subject:	Product Chemistry Data Review for Endosulfan Technical to Determine the Potential for Halogenated Dibenzo-p-Dioxin/Dibenzofuran Formation. I.D. No. 8340-13. Record No. 256248.
From:	S. Funk
To:	E. Feris
Dated:	2/8/90
MRID(s):	40623101-40623103

CBRS No(s).:	6089
Subject:	Product Chemistry Data Review for Endosulfan Technical to Determine the Potential for Halogenated Dibenzo-p-Dioxin/Dibenzofuran Formation. I.D. No. 11678-5.
From:	S. Funk
To:	E. Feris
Dated:	2/26/90
MRID(s):	40496601

DP Barcode(s):	D250579
Subject:	Hoechst Celanese Product Chemistry Data Reviewed in Support of the AgrEvo 96% T.
From:	K. Dockter
To:	S. DeVito
Dated:	11/3/98
MRID(s):	41421501-41421503, and 42932001-42932007

DP Barcode(s):	D250580
Subject:	Velsicol and Drexel Product Chemistry Data Reviewed in Support of the Drexel 95% T.
From:	K. Dockter
To:	S. DeVito
Dated:	11/4/98
MRID(s):	00129215, 42586701, 43244901, and 43268101

DP Barcode(s):	D250581
Subject:	Makhteshim Product Chemistry Data Reviewed in Support of the 95% T.
From:	K. Dockter
To:	S. DeVito
Dated:	11/5/98
MRID(s):	41537201, 42919101, and 42919102

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00003746 American Hoechst Corporation (1965) Data Sheet for Endosulfan/Thiodan. (Unpublished study received Aug 20, 1971 under 2H2667; CDL:225765-D)

00003821 Makhteshim Beer-Sheva Chemical Works, Limited (1969) Thionex: Insecticide. (Unpublished study received Jun 19, 1972 under 11678-5; CDL:011014-A)

00003772 Velsicol Chemical Corporation (19??) Technical Endosulfan Formulation Guide. Includes undated method. (Unpublished study received Sep 16, 1974 under 876-201; CDL:028577-A)

00128650 Makhteshim Beer-Sheva Chemical Works Ltd. (1983) Thionex 35 EC: End Use Product: [Chemistry Data]. (Compilation; unpublished study received May 31, 1983 under 11678-25; CDL:250400-A)

00128657 American Hoechst Corp. (1982) [Chemistry of Thiodan]. (Compilation; unpublished study received May 31, 1983 under 8340-13; CDL:250395-A)

00128661 Makhteshim Beer-Sheva Chemical Works, Ltd. (19??) Endosulfan Technical. (Compilation; unpublished study received May 31, 1983under 11678-5; CDL:250396-A)

00128662 Makhteshim Beer-Sheva Chemical Works, Ltd. (1983) [Chemistry of Thionex (Endosulfan) Technical]. (Compilation; unpublished study received May 31, 1983 under 11678-5; [rest of reference not given on fiche]

40496601 Registration Dept. Makhteshim Chemical Works Ltd. (1987) Thionex(Endosulfan)--Product Chemistry Data: Laboratory Project ID: R-4773. Unpublished study. 37 p.

00129215 Velsicol Chemical Corp. (1977) [Chemistry: Endosulfan]. (Compilation; unpublished study received Jul 14, 1983 under 876-201; CDL:250726-A)

00142995 Rexer, K.; Albrecht (1983) Storage Stability Studies for Endosulfan Substance, Technical: Bericht-Nr. WIR 0072 (31). Unpublished study prepared by Hoechst AG. 6 p.

00144958 - MRID citation unavailable

40496601 Registration Dept. Makhteshim Chemical Works Ltd. (1987) Thionex(Endosulfan)--Product Chemistry Data: Laboratory Project ID: R-4773. Unpublished study. 37 p.

40623101 Dehmer; Kaiser (1987) Endosulfan Technical: Description of Beginning Materials and Manufacturing Process: Laboratory Project No.87/2: A 36864. Unpublished compilation prepared by Hoechst Ag. 18 p.

40623102 Sarafin, R. (1987) HOE 002671 (Endosulfan): Discussion of the Formation of Impurities in the Technical Grade Substance: Laboratory Project No. (B) 179/87: A 36812. Unpublished compilation prepared by Hoechst Ag. 18 p.

40623103 Goerlitz, G. (1987) HOE 002671 (Endosulfan): Analysis for Poly-chlorinated Dibenzodioxins (PCDD) and Polychlorinated Dibenzofurans (PCDF): Laboratory Project No. (B) 189/87: A 36893. Unpublished compilation prepared by Hoechst Ag. 13 p.

41421501 Sarafin, R. (1982) HOE 002671 (Endosulfan), HOE 052618 (Alpha--Endosulfan) and HOE 052619 (Beta--Endosulfan)--Vapor Pressures: Lab Project Number: S 82/320: S 82/321: S 82/322. Unpublished study prepared by Hoechst Aktiengesellschaft. 20 p.

41421502 Asshauer, J. (1979) HOE 052618 and HOE 052619 (Alpha--and Beta Endosulfan): Solubility in Water: Lab Project Number: B 154/87: A 36704. Unpublished study prepared by Hoechst Aktiengesell-schaft. 13 p.

41421503 Asshauer, J.; Sarafin, R. (1979) HOE 052618 and HOE 052619 (Alpha & Beta--Endosulfan): Partition Coefficient Octanol/Water: Lab Project Number: B 124/87: Aceto Chemical Co., Inc., Flushing, Project Number: B 124/87: A 36576. Unpublished study prepared by Hoechst Aktiengesellschaft. 21 p.

41537201 Makhteshim Chemical Works Ltd. (1990) Discussion on the Potential for Halogenated Dibenzo-p-Dioxin/Dibenzofuran Formation in Endosulfan. Unpublished study. 11 p.

42586701 Haefele, L. (1992) Comments on the Improbability of Contamination of Drexel Endosulfan with Hexachlorobenzene and Pentachlorobenzene and with Halogenated Dibenzo-p-dioxins and Dibenzofurans. Unpublished study prepared by Drexel Chemical Co. 7 p.

42919101 Makhteshim Chemical Works, Ltd. (1993) Endosulfan Product Chemistry, Pesticide Assessment Guideline Series 61: Lab Project Number: R-7420. Unpublished study prepared by Makhteshim Chemical Works, Ltd. 103 p.

42919102 Ehmann, J. (1993) Hexachlorobenzene and Pentachlorobenzene Quantitation in Technical Endosulfan: Lab Project Number: 92 MAK 01. Unpublished study prepared by Institut Fresenius.108 p.

42932001 Hommel, K. (1992) Endosulfan (HOE 002671): Determination in the Technical Grade Active Ingredient and Formulations by Gas Chromatography, Using Internal Standard Calibration--Analytical Method: Lab Project Number: A 49026: AL 005/84-1. Unpublished study prepared by Hoechst Aktiengesellschaft. 11 p.

42932002 Gubert, M.; Hommel, K.; Weller, O. (1993) Determination of Secondary Components in HOE 002671 (Endosulfan)--Analytical Method: Lab Project Number: A 51151: AL 008/92-1. Unpublished study prepared by Hoechst Aktiengesellschaft. 12 p.

42932003 Gubert, M.; Hommel, K.; Weller, W. (1993) Determination of Toluene in Endosulfan (HOE 002671) Using Gas Chromatography with an Internal Standard Analytical Method: Lab Project Number: A 51150: AL 009/92-0. Unpublished study prepared by Hoechst Aktiengesellschaft. 11 p.

42932004 Weller, O.; Gubert, M.; Gubert, G. (1993) Validation of the Analytical Methods AL008/92-1 and AL009/92-0 for the Determination of Organic Impurities and Calibration--Analytical Determination of Organic Impurities and Toluene in Technical Endosulfan (HOE 002671): Lab Project Number: A 51217: CP93/041. Unpublished study prepared by Hoechst Aktiengesellschaft. 114 p.

42932005 Weller, O.; Weller, W. (1993) HOE 002671 (Endosulfan): Discussion of the Formation of Impurities in the Technical Grade Substance: Lab Project Number: A 51137: OE93/057. Unpublished study prepared by Hoechst Aktiengesellschaft. 17p.

42932006 Weller, O.; Gubert, M.; Gubert, C. (1993) Endosulfan (HOE002671): Analysis of Seven Typical Production Batches: Lab Project Number: A 51214: CP93/045. Unpublished study prepared by Hoechst Aktiengesellschaft. 100 p.

42932007 Ehmann, J. (1993) Hexachlorobenzene and Pentachlorobenzene Quantitation in Technical Endosulfan: Lab Project Number: A 51194: 92 HOE 01. Unpublished ties and Toluene in Technical51194: 92 HOE 01. Unpublished study prepared by Institut Fresenius Ingelheim. 104 p.

43244901 Claussen, F. (1994) Analysis of Endosulfan for Hexachlorobenzene and Pentachlorobenzene: Lab Project Number: 130S07. Unpublished study prepared by EPL Bio-Analytical Services, Inc. 58 p.

43268101 Handy, R. (1994) Product Identity and Composition Drexel Endosulfan Technical Insecticide. Unpublished study prepared by Drexel Chemical Co. 13 p.

Case No. 0014
Chemical No. 079401

Case Name: Endosulfan
Registrant: AgrEvo USA Company
Product(s): 96% T (EPA Reg No. 45639-168)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N [3]	00128657
830.1600	Description of materials used to produce the product	N [4]	00128657, 00144958
830.1620	Description of production process	N [4]	00128657, 00144958
830.1670	Discussion of formation of impurities	Y	00144958, 40623101-40623103 [5], *42932005*
830.1700	Preliminary analysis	Y	*42932006, 42932007*
830.1750	Certified limits	N [6]	00128657
830.1800	Enforcement analytical method	Y	00128657, *42932001-42932004*
830.6302	Color	Y	00128657
830.6303	Physical state	Y	00128657
830.6304	Odor	Y	00128657
830.6313	Stability to normal and elevated temperature, metals, and metal ions	Y	00128657
830.6314	Oxidation/reduction: chemical incompatibility	N	
830.6315	Flammability	N/A [7]	
830.6316	Explodability	N	
830.6317	Storage stability	Y	00142995
830.6319	Miscibility	N/A [7]	
830.6320	Corrosion characteristics	N	
830.7000	pH	Y	00128657
830.7050	UV/visible absorption	N [8]	
830.7100	Viscosity	N/A [7]	
830.7200	Melting point/melting range	Y	00128657
830.7220	Boiling point/boiling range	N/A [7]	
830.7300	Density/relative density/bulk density	Y	00128657
830.7370	Dissociation constants in water	N/A [9]	
830.7550	Partition coefficient (*n*-octanol/water), shake flask method	Y	00128657, *41421503*
830.7840	Water solubility: column elution method; shake flask method	Y	**00003746**, *41421502*
830.7950	Vapor pressure	Y	00128657, *41421501*

[1] Y = Yes; N = No; N/A = Not Applicable. This product was transferred from Hoechst Celanese Corp. (EPA Reg. No. 8340-13); the data summary table reflects data submitted by Hoechst. AgrEvo must confirm that the manufacturing process and site have not changed since the product transfer; otherwise, all product chemistry data will be required.

[2] **Bolded** reference was reviewed in the Endosulfan Registration Standard Product Chemistry Chapter dated 9/17/81; *italicized* references were reviewed under DP Barcode D250579, 11/3/98, K. Dockter, and remaining references were reviewed in the Endosulfan Reregistration Standard Update dated 8/9/90 unless otherwise noted.

[3] An updated CSF must be submitted including nominal concentrations for the active ingredient and impurities present at $0.1%.

[4] The following additional information must be submitted: (I) a statement as to whether the process is batch or continuous; (ii) the duration of each step and of the entire process; (iii) the relative amounts of the materials used; (iv) a description of the manufacturing equipment; (v) a complete description of the reaction conditions controlled (e.g. pH, pressure) during each step of the process; and (vi) a description of the sampling regimen and quality control procedures necessary to assure product consistency.

[5] Reviewed for dioxin DCI; CBRS No. 6087, 2/8/90, S. Funk.

[6] An updated CSF must be submitted which properly identifies the current registrant and EPA Reg. No. We note that certified limits should be based on the results of preliminary analysis.

[7] Data are not required because the T/TGAI is a solid at room temperature.

[8] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

[9] Data are not required because the TGAI is not an acid or base.

Case No. 0014
Chemical No. 079401

Case Name: Endosulfan
Registrant: FMC Corporation
Product(s): 95% T (EPA Reg No. 279-2306)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N [3]	CSF 2/27/84
830.1600	Description of materials used to produce the product	N	
830.1620	Description of production process	N	
830.1670	Discussion of formation of impurities	N	
830.1700	Preliminary analysis	N	
830.1750	Certified limits	N [3]	CSF 2/27/84
830.1800	Enforcement analytical method	N	
830.6302	Color	N	
830.6303	Physical state	N	
830.6304	Odor	N	
830.6313	Stability to normal and elevated temperature, metals, and metal ions	N	
830.6314	Oxidation/reduction: chemical incompatibility	N	
830.6315	Flammability	N/A [4]	
830.6316	Explodability	N	
830.6317	Storage stability	N	
830.6319	Miscibility	N/A [4]	
830.6320	Corrosion characteristics	N	
830.7000	pH	N	
830.7050	UV/visible absorption	N [5]	
830.7100	Viscosity	N/A [4]	
830.7200	Melting point/melting range	N	
830.7220	Boiling point/boiling range	N/A [4]	
830.7300	Density/relative density/bulk density	N	
830.7370	Dissociation constants in water	N/A [6]	
830.7550	Partition coefficient (*n*-octanol/water), shake flask method	N	
830.7840	Water solubility: column elution method; shake flask method	N	
830.7950	Vapor pressure	N	

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] The CSF was reviewed in the Endosulfan Reregistration Standard Update dated 8/9/90.

[3] An updated CSF must be provided on which the impurities are correctly identified, nominal concentrations are provided for the appropriate ingredients, and the source of the ai is correctly identified. If the product is repackaged

from an EPA-registered product, then all data requirements will be fulfilled by the technical source product; otherwise, all product chemistry data will be required.

[4] Data are not required because the T/TGAI is a solid at room temperature.

[5] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

[6] Data are not required because the TGAI is not an acid or base.

Case No. 0014
Chemical No. 079401

Case Name: Endosulfan
Registrant: Drexel Chemical Company
Product(s): 95% T (EPA Reg No. 19713-319)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N [3]	CSF dated 6/13/83
830.1600	Description of materials used to produce the product	Y	**00003772**, 00129215, 43268101
830.1620	Description of production process	Y	**00003772**, 00129215, 43268101
830.1670	Discussion of formation of impurities	Y	00129215, 42586701, 43268101
830.1700	Preliminary analysis	N [4]	43244901
830.1750	Certified limits	N [5]	CSF dated 6/13/83
830.1800	Enforcement analytical method	N [6]	00129215, 43268101
830.6302	Color	Y	**00003772**, 00129215
830.6303	Physical state	Y	00129215
830.6304	Odor	Y	**00003772**, 00129215
830.6313	Stability to normal and elevated temperature, metals, and metal ions	Y	**00003772**, 00129215
830.6314	Oxidation/reduction: chemical incompatibility	N	
830.6315	Flammability	N/A [7]	
830.6316	Explodability	Y	**00003772**
830.6317	Storage stability	N	
830.6319	Miscibility	N/A [7]	
830.6320	Corrosion characteristics	Y	00129215
830.7000	pH	N [8]	00129215
830.7050	UV/visible absorption	N [9]	
830.7100	Viscosity	N/A [7]	
830.7200	Melting point/melting range	Y	**00003772**, 00129215
830.7220	Boiling point/boiling range	N/A [7]	
830.7300	Density/relative density/bulk density	Y	**00003772**, 00129215
830.7370	Dissociation constants in water	N/A [10]	
830.7550	Partition coefficient (*n*-octanol/water), shake flask method	N	
830.7840	Water solubility: column elution method; shake flask method	Y	00129215
830.7950	Vapor pressure	Y	00129215

[1] Y = Yes; N = No; N/A = Not Applicable. This product was transferred from Velsicol Agricultural Chemicals (EPA Reg. No. 876-201); the data summary table includes data submitted by both Velsicol and Drexel. Drexel

must confirm that the manufacturing process and site have not changed since the product transfer; otherwise, additional product chemistry data will be required.

[2] **Bolded** references were reviewed in the Product Chemistry Chapter of the Endosulfan Reregistration Standard dated 9/17/81, and all other references wer reviewed under DP Barcode 250580, 11/4/98, K. Dockter.

[3] An updated CSF must submitted including nominal concentrations for the active ingredient, and each inert ingredient and impurity present at $0.1%.

[4] Data reflecting preliminary analysis of five batches of the T/TGAI for the active ingredient and impurities present at $0.1% are required.

[5] An updated CSF must be submitted which properly identifies the current registrant and EPA Registry Number, and an upper certified limit must be proposed for the active ingredient.

[6] Validation data (accuracy and precision) are required for the active ingredient and impurities related to the active ingredient present at $0.1%.

[7] Data are not required because the T/TGAI is a solid at room temperature.

[8] Quantitative data must be submitted.

[9] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

[10] Data are not required because the TGAI is not an acid or base.

Case No. 0014
Chemical No. 079401

Case Name: Endosulfan
Registrant: Makhteshim Chemical Works Limited
Product(s): 95% T (EPA Reg No. 11678-5)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N [3]	00128662, 40496601 [4]
830.1600	Description of materials used to produce the product	Y	00128662, 40496601 [4], *42919101*
830.1620	Description of production process	Y	00128662, 40496601 [4], *42919101*
830.1670	Discussion of formation of impurities	Y	00128662, 40496601 [4], *41537201, 42919101*
830.1700	Preliminary analysis	N [5]	00128662, *42919102*
830.1750	Certified limits	N [3]	00128662
830.1800	Enforcement analytical method	N [6]	00128662
830.6302	Color	Y	00128661
830.6303	Physical state	Y	00128661
830.6304	Odor	Y	00128661
830.6313	Stability to normal and elevated temperature, metals, and metal ions	Y	00128661
830.6314	Oxidation/reduction: chemical incompatibility	Y	00128662
830.6315	Flammability	N/A [7]	
830.6316	Explodability	Y	00128662
830.6317	Storage stability	Y	00128662
830.6319	Miscibility	N/A [7]	
830.6320	Corrosion characteristics	N	
830.7000	pH	Y	00128661
830.7050	UV/visible absorption	N [8]	
830.7100	Viscosity	N/A [7]	
830.7200	Melting point/melting range	Y	00128661
830.7220	Boiling point/boiling range	N/A [7]	
830.7300	Density/relative density/bulk density	Y	00128661
830.7370	Dissociation constants in water	N/A [9]	
830.7550	Partition coefficient (*n*-octanol/water), shake flask method	Y	00128661
830.7840	Water solubility: column elution method; shake flask method	Y	**00003821**
830.7950	Vapor pressure	Y	00128661

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] **Bolded** references were reviewed in the Endosulfan Registration Standard Product Chemistry Chapter dated 9/17/81; *italicized* references were reviewed under DP Barcode D250581, 11/5/98, K. Dockter; and remaining references were reviewed in the Endosulfan Reregistration Standard Update dated 8/9/90 unless otherwise noted.

[3] An updated CSF must be submitted on EPA Form 8570-4 which correctly identifies the impurities and provides appropriate nominal concentrations and certified limits.

[4] CBRS No. 6089, 2/26/90, S. Funk.

[5] Preliminary analysis data have been reviewed; however, raw data for the active ingredient and impurities, means and standard deviations for all ingredients, and the analytical methods used (including validation data) must be submitted.

[6] Supporting validation data must be submitted for the analytical methods proposed for enforcement of the active ingredient and impurities.

[7] Data are not required because the T/TGAI is a solid at room temperature.

[8] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

[9] Data are not required because the TGAI is not an acid or base.

Case No. 0014
Chemical No. 079401

Case Name: Endosulfan
Registrant: Makhteshim Chemical Works Limited
Product(s): 35% FI (EPA Reg. No. 11678-25)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N [3]	00128650
830.1600	Description of materials used to produce the product	N [4]	00128650
830.1620	Description of formulation process	N [4]	00128650
830.1670	Discussion of formation of impurities	N [5]	00128650
830.1700	Preliminary analysis	N/A [6]	
830.1750	Certified limits	N [3]	00128650
830.1800	Enforcement analytical method	N [7]	00128662
830.6302	Color	Y	00128650
830.6303	Physical state	Y	00128650
830.6304	Odor	Y	00128650
830.6313	Stability to normal and elevated temperature, metals, and metal ions	N/A [6]	
830.6314	Oxidation/reduction: chemical incompatibility	Y	00128650
830.6315	Flammability	Y	00128650
830.6316	Explodability	Y	00128650
830.6317	Storage stability	Y	00128650
830.6319	Miscibility	Y	00128650
830.6320	Corrosion characteristics	Y	00128650
830.7000	pH	Y	00128650
830.7050	UV/visible absorption	N/A [6]	
830.7100	Viscosity	Y	00128650
830.7200	Melting point/melting range	N/A [6]	
830.7220	Boiling point/boiling range	N/A [6]	
830.7300	Density/relative density/bulk density	Y	00128650
830.7370	Dissociation constants in water	N/A [6]	
830.7550	Partition coefficient (*n*-octanol/water), shake flask method	N/A [6]	
830.7840	Water solubility: column elution method; shake flask method	N/A [6]	
830.7950	Vapor pressure	N/A [6]	

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] All references were reviewed in the Endosulfan Reregistration Standard Update dated 8/9/90.

[3] A revised CSF must be submitted. The nominal concentration for the active ingredient must reflect the actual level of the active ingredient in the product (based on the nominal concentration of the source product), and upper and lower certified limits must be proposed for all inert ingredients

[4] A description of the formulation process including mixing conditions (pH, temperature), addition order of ingredients, duration of the process, and quality control procedures must be submitted.

[5] A discussion must be submitted concerning the potential for formation of impurities from (I) the degradation of the ingredients in the product after production but prior to use; (ii) post-production reactions between the ingredients in the product; (iii) the migration of components of packaging materials into the product; (iv) the carryover of contaminants from use of production equipment to produce other products or substances; and (v) the process control, purification procedures, and quality control measures used to produce the product.

[6] Data requirements for the TGAI will be satisfied by data for the technical source product.

[7] Supporting validation data must be submitted for the analytical methods proposed for the enforcement of the active ingredients and impurities.